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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/844,268	07/25/2001	Brad T. Bosworth	21419/91513	9905
23644	7590	06/27/2006	EXAMINER	
BARNES & THORNBURG, LLP P.O. BOX 2786 CHICAGO, IL 60690-2786			WOITACH, JOSEPH T	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 06/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/844,268

Applicant(s)

BOSWORTH ET AL.

Examiner

Joseph T. Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2006.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,4,6 and 7 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 2 is/are allowed.  
6) ☒ Claim(s) 4 and 7 is/are rejected.  
7) ☒ Claim(s) 6 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 25 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This application filed April 27, 2001 is a continuation of 09/443,766 filed November 19, 1999, which claims benefit under 35 U.S.C. 120 to PCT/US98/10318, filed May 20, 1998, which claims benefit to provisional application 60/047,181, filed May 20, 1997.

Applicants amendment filed April 4, 2006, has been received and entered. Claims 1, 3, 5-11 have been canceled. Claims 2, 4, 6 and 7 have been amended. Claims 2, 4, 6 and 7 are pending and currently under examination.

### ***Claim Objections***

Claim 6 stands objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 2 has been amended to encompass SEQ ID NO: 12 wherein position 307 is altered. Claim 6 appears to encompass a different sequence with a different or additional alterations to SEQ ID NO: 12. However providing a different sequence or further alterations does not further limit claim 2, it expands the metes and bounds suggesting that claim 2 in fact would encompass any number and kinds of alterations which is not supported by the specification.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 6 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Upon review of the amendments to the claims Examiner would agree that the language and embodiments of claims 2 and 6 are not indefinite.

Claim 7 rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation and embodiments encompassed by “distinguishes” is withdrawn.

More clearly setting forth that a polymorphism is being detected has obviated the basis of the rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Larsen *et al.* (1990))(as evidenced by Meijerink *et al.*, 1997).

Applicants argue that SEQ ID NO: 12 is not human and that it is improper to rely on the post filing art of Meijerink *et al.* See Applicants’ amendment, pages 3-4, section III.

Applicants’ arguments have been fully considered, but not found persuasive.

Examiner acknowledges that Larsen *et al.* does not teach a porcine sequence, however in the examination of a product review of relevant art for anticipation simply requires a reasonable interpretation of the metes and bounds of the claims and an analysis of the prior art to anticipate the interpretation. Applicants have not argued the assertion that claim 4 simply requires a sequence that is complimentary to SEQ ID NO: 12, and similarly claim 7 requires only a sequence that can be used to identify SEQ ID NO 12 for the intended use to distinguish resistance (there is no requirement that the sequence used comprises any specific sequence to this intended use and comprises analyzing for any potential polymorphism), nor that the human sequence of Larsen *et al.* comprises fragments that are complimentary to SEQ ID NO: 12 (as evidenced by Meijerink *et al.*). Again, neither claim 4 nor 7 requires a sequence that is unique from only SEQ ID NO: 12. Larsen *et al.* teach the isolation of a cDNA encoding human FUT 1 and provide the specific sequences encoding the protein sequence, which comprises sequence that are homologous to SEQ ID NO: 12 (see for example figure 3A of Meijerink *et al.*). Since a reasonable interpretation of the claims encompasses a fragment of SE ID NO: 12, the teaching of Larsen *et al.* providing human FUT1 that is homologous to porcine FUT1 anticipates the instant claims.

Claims 4 and 7 stand rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5,474,796- issued Dec 1995).

Applicants argue that Brennan does not teach SEQ ID NO: 12, and that it is an unreasonable interpretation of the claims to encompass tri-nucleotide fragments. See

Applicants' amendment, page 4, section IV. Applicants' arguments have been fully considered, but not found persuasive.

Initially, it is noted that claim 7 recites a "fragment of the isolated DNA molecule" without setting forth the size of said fragment or any specific functional requirement for any intended use. Applicants arguments that the interpretation of the breadth of the claim(s) as unreasonable is not found convincing because there is no support for any size limitation in the claim nor the specification. Applicants have simply stated that the interpretation is unreasonable without providing a basis for this assertion. Examiner acknowledges that Brennan does not teach SEQ ID NO: 12, nor any specific polymorphism, however as discussed above, all that is required for anticipation of the instant claims is a teaching of a DNA fragment of any size that is complimentary to SEQ ID NO: 12. In this case, the disclosure of Brennan of DNA oligonucleotide 10mers provides for sequences that are complementary

### ***Conclusion***

Claim 2 is allowed. Claim 6 is objected to for not further limiting, but may be found allowable if drafted to comprise SEQ ID NO: 12 comprising an alteration in position 229 (similar to claim 2). Additionally, a claim comprising both alterations in a single sequence comprising SEQ ID NO: 12 may also be found allowable.

As noted previously, the art indicates that cell surface receptors on intestinal cells are the target molecules for *E. coli* colonization, and that the glycosylation on said receptors may be important in determining the ability of a particular *E. coli* to colonize the intestine. However, the art fails to specifically teach that an adenine at position 307 of the open reading frame of alpha

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(1,2) fucosyltransferase (FUT1) (SEQ ID NO: 12) can be correlated with resistance to *E. coli* strain F18 and possibly with the subsequent associated diseases. However, the breadth of the claims encompassing complementary sequences that can be fragments and fragments with the intended use of detecting polymorphisms are products which were disclosed in the prior art given the breadth of the claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Voitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach

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AU 1632